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Exhibit 187

CLAAD Center for Lawful Access and Abuse Deterrence

December XX, 2015

The Honorable Sylvia Mathews Burwell
Secretary
U.S. Department of Health and Human Services
200 Independence Ave, S.W.
Washington, DC 20201

Dear Secretary Burwell:

The undersigned organizations are encouraged by your September announcement that the Department of Health and Human Services (HHS) will expand access to medication-assisted treatment for opioid dependence (MAT) by revising the "regulations related to buprenorphine to safely and effectively increase access."[1] As you acknowledged, the new regulations must enhance lawful access to this important medication for use in evidence-based MAT while simultaneously minimizing the risk of drug diversion.[2]

As you draft new HHS regulations for buprenorphine prescribing, we encourage you to look to The Recovery Enhancement for Addiction Treatment Act, H.R. 2536, (TREAT Act) as a viable starting point. The TREAT Act proposes to expand buprenorphine access, improve the quality of care, and help reduce buprenorphine diversion, misuse, abuse, and accidental exposure in the following ways:

- The bill would increase the initial buprenorphine patient limit for qualified practitioners from 30 to 100 patients. A recent study showed that increasing the patient limit for physicians from 30 to 100 resulted in significant expansion of buprenorphine treatment.[3] The study ultimately concluded that providers are more likely to seek waivers to prescribe buprenorphine if they are approved to treat 100 patients (rather than 30) with buprenorphine.[4] Allowing qualified physicians and advanced practitioners to prescribe to up to 100 patients is a significant improvement that could result in qualified practitioners developing practices that focus on treatment of substance use disorders and prescribing buprenorphine for addiction treatment.

- The definition of "qualified practitioners" would include advanced practitioners (*i.e.*, nurse practitioners and physician assistants). Granting buprenorphine-prescribing authority to advanced practitioners in the manner proposed in the TREAT Act would expand patient

[1] Sylvia Matthews Burwell, *50-State Convening to Prevent Opioid Overdose and Addiction*, U.S. DEP'T OF HEALTH & HUMAN SERVICES, http://www.hhs.gov/about/leadership/secretary/speeches/2015/50-state-convening-prevent-opioid-overdose-and-addiction.html (last visited Nov. 11, 2015).
[2] *HHS hosts 50-state convening focused on preventing opioid overdose and opioid use disorder, takes important step to increase access to treatment*, U.S. DEP'T OF HEALTH & HUMAN SERVICES, http://www.hhs.gov/news/press/2015pres/09/20150917a.html (last visited Sept. 17, 2015).
[3] Bradley D. Stein et al., *Where Is Buprenorphine Dispensed to Treat Opioid Use Disorders? The Role of Private Offices, Opioid Treatment Programs, and Substance Abuse Treatment Facilities in Urban and Rural Counties*, 93 MILBANK Q. 3, 561, 576 (2015).
[4] *Id.* at 577

access to a greater number of specialists and better allocate health care human resources, especially in rural areas of the country.

- For a practitioner to exceed the 100 patient limit, the bill would impose either certification requirements or restrictions in treatment setting, thereby improving quality of care.

- The bill would require practitioners to participate in their state's prescription drug monitoring program (PDMP), reducing the likelihood of diversion, misuse, abuse, and accidental exposure.

We recommend that the HHS regulations incorporate the following improvements to the proposals set forth in the TREAT Act:

- Set an upper limit on the number of patients that a practitioner may treat with buprenorphine for opioid dependence.

- Given that qualified physicians will have expanded access to 100 patients without a certification requirement or treatment setting restriction, impose quality of care and diversion prevention measures for these physicians.

The new regulations should also exempt certain patient populations that have a reduced risk for diversion and abuse. These populations include persons who are stable in recovery, pregnant women, and individuals whose buprenorphine is administered by a qualified practitioner in the form of an implant or injectable.

Practitioners achieving successful clinical outcomes with long-term patients who have adhered to their treatment plan should be strongly encouraged to treat additional patients and not be forced to terminate treatment of existing patients in order to treat new patients on wait lists. Treatment stability may be indicated if definitive urine drug test results, conducted over a six-month period, show the presence of buprenorphine and the absence of non-prescribed or illicit substances.

Pregnant women seeking treatment out of concern for fetal well-being are substantially more likely to adhere to the treatment plan and pose a lower risk of medication diversion and abuse, and should receive treatment on demand. Delays in treatment during pregnancy can lead to opioid withdrawal and severe effects on fetal development. Buprenorphine has been shown to be effective in improving neo-natal clinical outcomes and reducing the presence and severity of neo-natal abstinence syndrome.

Implantable and injectable buprenorphine is inherently less susceptible to diversion, misuse, abuse, and accidental exposure than products dispensed to patients for self-administration. In fact, the National Institute on Drug Abuse (NIDA) funded the development of a buprenorphine implant.[5] Long-acting buprenorphine implants and injectables are under

[5] *Titan Announces Award of NIH Grant for Probuphine™ Clinical Development*, http://www.titanpharm.com/press/2009/091001-press-rel-probuphine.htm (last visited Nov. 3, 2015).

development, with one potential buprenorphine implant, Probuphine, expected to be available in early 2016.

Consistent with the Office of National Drug Control Policy's stated objective of fostering development and use of abuse-deterrent opioids,[6] it is important for the U.S. Food and Drug Administration to clarify that implantables and injectables that are never dispensed to patients may be appropriately labeled as abuse deterrent without undergoing the types of manipulation tests appropriate when evaluating the potential for abuse of oral drug products dispensed to patients for self-administration.

Finally, we wish to express our concern that other opioid abuse reduction initiatives undertaken by HHS agencies do not reflect the commitment to moderation that your MAT announcement embodied. Individuals with legitimate medical needs for controlled prescription medications must be able to access them regardless of their particular health condition. Yet, the Draft Guidelines for Prescribing Opioids for Chronic Pain proposed by the Centers for Disease Control and Prevention (CDC) on September 16, 2015, appear to sacrifice the priority of meeting the medical needs of individuals with pain in favor of preventing opioid analgesic diversion and abuse. We urge HHS to direct the CDC to ensure that the final CDC guidelines prioritize lawful access and abuse deterrence *equally*.

We urge you to take these actions in a timely manner to meet the challenges we are facing across the country today. More comprehensive policy proposals to advance the dual public health goals of lawful medication access and abuse deterrence are set forth in the 2009 through 2015 iterations of the Center for Lawful Access and Abuse Deterrence's *National Prescription Drug Abuse Prevention Strategy*, which have been vetted and endorsed by 30 or more not-for-profit public health and safety organizations. If you or your staff have any questions regarding these proposals, please contact Marcus Garza of the Center for Lawful Access and Abuse Deterrence at (202) 599-8435 or mgarza@claad.org.

Sincerely,

Center for Lawful Access and Abuse Deterrence
Association of Women's Health, Obstetric and Neonatal Nurses

Cc: Paul T. Dioguardi, Director
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Myisha Gatson, MPA, Associate Director of External Affairs and Policy

[6] *Epidemic: Responding to America's Prescription Drug Abuse*, WHITE HOUSE OFFICE OF NAT'L DRUG CONTROL POLICY, https://www.whitehouse.gov/sites/default/files/ondcp/issues-content/prescription-drugs/rx_abuse_plan.pdf (last visited Nov. 3, 2015).

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